

REMARKS/ARGUMENTS

Status of Claims

Claims 3 and 12 have been amended.

Claims 13-14, 24-25, 28 and 30-33 have been canceled.

Thus, claims 1-12, 15-23, 26, 27, and 29 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed

Claims Objection

Applicants have amended claims 3 and 12 to correct the informalities pointed out by the Office Action and respectfully request that the objections be withdrawn.

Claims Rejection – 35 U.S.C. § 103

Claims 1-3 and 29 stand rejected under 35 U.S.C § 103(a) as being unpatentable over EP 325571 A1 (hereinafter “*the ‘571 patent*”). Claims 2, 3, and 29 depend from claim 1. Thus, the pending claims stand or fall on the application of *the ‘571 patent* to claim 1. As noted by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, an obviousness determination begins with a finding that “the prior art as a whole in one form or another contains all” the elements of the claimed invention. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966). Applicants submit *the ‘571 patent* does not contain all of the elements of the claimed invention.

Claim 1 recites “[r]acemic tolterodine free base in crystalline form.” Applicants respectfully submit that the prior art of record fails to teach or suggest that racemic tolterodine free base could even exist in crystalline form. Thus, the cited art does not suggest the claimed crystalline form of the racemic tolterodine free base or suitable methods of obtaining the

crystalline form. Referring to *the '571 patent*, N-N-diisopropyl-3-(2-hydroxy-5-methylphenyl)-3-phenylpropyl-amine hydrochloride (tolterodine hydrochloride) of Example 9G is produced from the methoxy-protected fumarate compound of Example 5D, which was produced from the methoxy-toluene sulphonate-protected compound of Example 4B. Thus, *the '571 patent* is silent as to the presently claimed racemic tolterodine free base in crystalline form or a methodology for obtaining same.

Applicants' further use of the novel racemic tolterodine free base in crystalline form provides further evidence of the non-obviousness of the claimed racemic tolterodine free base in crystalline form. As noted in MPEP 2144.04

“Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include **whether the claimed chemical compound or composition has the same utility** as closely related materials in the prior art, and **whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure.** *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966) (emphasis added)

Applicants submit the differing utility of the racemic tolterodine free base in crystalline form is disclosed on page 4 of the instant application:

“There is now provided by the present invention racemic tolterodine free base in crystalline form which in turn can allow the preparation of substantially pure (+) tolterodine tartarate.”

Thus, Applicants disclose the ability to prepare a substantially pure derivative ((+)tolterodine tartarate) from the claimed racemic tolterodine free base in crystalline form, a utility not disclosed by the cited reference. In consideration of the foregoing Applicants respectfully submit claim 1 and all claims depending therefrom are patentable over *the '571 patent*.

Claims 4-12 stand rejected under 35 U.S.C § 103(a) as obvious over CN 1364757 (hereinafter “*the '757 patent*”). Claims 5-12 depend from claim 4, thus the pending claims stand

or fall on the application of *the '757 patent* to claim 4. As noted by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, an obviousness determination begins with a finding that “the prior art as a whole in one form or another contains all” the elements of the claimed invention. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966). Applicants submit *the '757 patent* does not contain all of the elements of the claimed invention. Specifically, Applicants fail to find disclosure of the crystalline form of the racemic tolterodine free base in *the '757 patent*. Applicants direct the Examiner’s attention to Example 4 of *the '757 patent*, which discloses that the product is isolated as the hydrochloride salt having a melting point of 210 °C. A similar melting point is disclosed for tolterodine hydrochloride in *the '571 patent*, see Example 9C. Thus, *the '757 patent* and *the '571 patent* disclose the same form of tolterodine hydrochloride salt, which is not the same as the presently claimed racemic tolterodine free base in crystalline form and methods of making same. Consequently *the '757 patent* does not teach or suggest all of the elements of independent claim 4, and thus claim 4 and all claims depending there from are patentable over *the '757 patent*.

Allowable Subject Matter

Applicants note with appreciation that claims 15-23, 26, and 27 contain allowable subject matter.

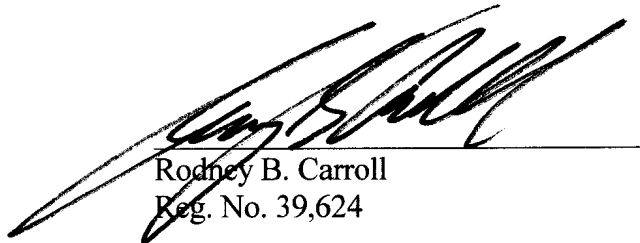
CONCLUSION

Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections is respectfully requested by Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated June 12, 2008 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,
CONLEY ROSE, P.C.

Date: 11-12-08



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